K021251

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9.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. The submitter of this premarket notification is:

Dave Osborn
Regulatory Affairs Engineer
Cardiac & Monitoring Systems Group
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1085

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This summary was prepared on 17 April, 2002

2. The name of this device is the Philips ST/AR ST and Arrhythmia Software, Release E.1. Classification names are as follows:

Classification	ProCode	Description
870.1025, III	74 MLD	Monitor, ST Alarm
870.1025, III	74 DSI	Arrhythmia Detector and Alarm
None	74 MHX	Physiological Monitor, Patient Monitor

3. The new device is substantially equivalent to the previously cleared ST/AR ST and Arrhythmia Software device marketed pursuant to K964122, K991773, K001348, K003621 and K014261.

4. The modification is a software-based change that provides Cardiotach functionality without arrhythmia analysis and ST Segment Analysis without arrhythmia analysis.

5. The new device has the same Indications for Use as the legally marketed predicate device. Where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

6. The new device has the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved

system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that ST/AR Release E.1 meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 07 2002

Mr. Dave Osborn
Quality Program Manager
Philips Medical Systems
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, MA 01810-1099

Re: K021251
Trade Name: Philips Medical Systems ST/AR and Arrhythmia Software, Release E.1.
Regulation Name: Arrhythmia Detector and Alarm
Regulation Number: 21 CFR 870.1025
Regulatory Class: Class III (three)
Product Code: DSI
Dated: April 18, 2002
Received: April 19, 2002

Dear Mr. Osborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021251

Device Name: Philips Medical Systems ST/AR Software, Release E.1.

Indications for Use: Where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

The intended use of the ST/AR cardiotach is to monitor a neonatal, pediatric, or adult patient's ECG for heart rate and produce events/alarms for one or two ECG leads. The cardiotach function is capable of monitoring both paced and non-paced patients.

The intended use of the ST/AR arrhythmia analysis algorithm is to monitor a neonatal, pediatric, or adult patient ECG's for heart rate and ventricular arrhythmias and produce events/alarms for one or two ECG leads. The arrhythmia analysis algorithm is capable of monitoring both paced and non-paced patients.

The intended use of the ST/AR ST analysis algorithm is to monitor an adult patient's ECG for ST segment elevation or depression and produce events/alarms for all possible ECG leads. The ST analysis algorithm is capable of monitoring paced and non-paced adult patients.

Note: The ST algorithm does not analyze ventricularly paced or ventricular ectopic beats.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use**

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices

510(k) Number K021251